

by the written consent of the individual named.

(f) The names and any information that would identify the voluntary reporter or any other person associated with an adverse event involving a human drug, biologic, or medical device product shall not be disclosed by the Food and Drug Administration or by a manufacturer in possession of such reports in response to a request, demand, or order. Information that would identify the voluntary reporter or persons identified in the report includes, but is not limited to, the name, address, institution, or any other information that would lead to the identities of the reporter or persons identified in a report. This provision does not affect disclosure of the identities of reporters required by a Federal statute or regulation to make adverse event reports. Disclosure of the identities of such reporters is governed by the applicable Federal statutes and regulations.

(1) *Exceptions.* (i) Identities may be disclosed if both the voluntary reporter and the person identified in an adverse event report or that person's legal representative consent in writing to disclosure, but neither FDA nor any manufacturer in possession of such reports shall be required to seek consent for disclosure from the voluntary reporter or the person identified in the adverse event report or that person's legal representative; or

(ii) Identities of the voluntary reporter and the person who experienced the reported adverse event may be disclosed pursuant to a court order in the course of medical malpractice litigation involving both parties; or (iii) The report, excluding the identities of any other individuals, shall be disclosed to the person who is the subject of the report upon request.

(2) *Preemption.* No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement that permits or requires disclosure of the identities of the voluntary reporter or other person identified in an adverse event report except as provided in this section.

[42 FR 15616, Mar. 22, 1977, as amended at 60 FR 16968, Apr. 3, 1995]

§ 20.64 Records or information compiled for law enforcement purposes.

(a) Records or information compiled for law enforcement purposes may be withheld from public disclosure pursuant to the provisions of this section to the extent that disclosure of such records or information:

(1) Could reasonably be expected to interfere with enforcement proceedings;

(2) Would deprive a person of a right to a fair trial or an impartial adjudication;

(3) Could reasonably be expected to constitute an unwarranted invasion of personal privacy;

(4) Could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis; and information furnished by a confidential source in the case of a record compiled by the Food and Drug Administration or any other criminal law enforcement authority in the course of a criminal investigation or by an agency conducting a lawful national security intelligence investigation;

(5) Would disclose techniques and procedures for law enforcement investigations or prosecutions or would disclose guidelines for law enforcement investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law; or

(6) Could reasonably be expected to endanger the life or physical safety of any individual.

(b) Records include all records relating to regulatory enforcement action, including both administrative and court action, which have not been disclosed to any member of the public, including any person who is the subject of the investigation.

(c) Any record which is disclosed to any person, including any person who is the subject of a Food and Drug Administration investigation, and any data or information received from any person who is the subject of a Food and Drug Administration investigation relating to such investigation, is available for public disclosure at that time

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in accordance with the rule established in § 20.21, except that:

(1) Disclosure of such records shall be subject to the other exemptions established in this subpart and to the limitations on exemptions established in subpart E of this part.

(2) The record of a section 305 hearing shall be available for public disclosure only in accordance with the provisions of § 7.87 of this chapter.

(d) Records for law enforcement purposes shall be subject to the following rules:

(1) No such record is available for public disclosure prior to the consideration of regulatory enforcement action based upon that record's being closed, except as provided in § 20.82. The Commissioner will exercise his discretion to disclose records relating to possible criminal prosecution pursuant to § 20.82 prior to consideration of criminal prosecution being closed only very rarely and only under circumstances that demonstrate a compelling public interest.

(2) After the consideration of regulatory enforcement action is closed, such records shall be made available for public disclosure except to the extent that other exemptions from disclosure in this subpart are applicable. No statements of witnesses obtained through promises of confidentiality are available for public disclosure.

(3) The consideration of regulatory enforcement action based upon a particular record shall be deemed to be closed within the meaning of this section:

(i) If it relates to administrative action, when a final decision has been made not to take such action or such action has been taken and the matter has been concluded.

(ii) If it relates to court action, when a final decision has been made not to recommend such action to a United States attorney based upon that record, or a recommendation has been finally refused by a United States attorney, or court action has been instituted and the matter and all related appeals have been concluded, or the statute of limitations runs.

(iii) If it relates to both administrative and court action, when the events

described in both paragraph (d)(3) (i) and (ii) of this section have occurred.

(4) Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

(e) Names and other information that would identify a Food and Drug Administration employee shall be deleted from records prior to public disclosure only pursuant to § 20.32.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 536, Jan. 5, 1994]

Subpart E—Limitations on Exemptions

§ 20.80 Applicability of limitations on exemptions.

(a) The limitations on exemptions established in this subpart shall apply to all Food and Drug Administration records, except as specifically provided herein. Accordingly, a record that is ordinarily exempt from public disclosure in accordance with the provisions in subpart D of this part is available for such disclosure to the extent that it falls within a limitation on the exemption contained in this subpart. For example, an investigatory record that is ordinarily exempt from disclosure under § 20.64 is disclosable to Congress in accordance with the provisions of § 20.87.

(b) Disclosure of a record to any member of the public pursuant to the provisions in § 20.81, data and information previously disclosed to the public, in § 20.82, discretionary disclosure by the Commissioner, and in § 20.83, disclosure pursuant to a court order, shall involve the rule established in § 20.21 that the record shall be made available for disclosure to all members of the public who request it. Disclosure of a record only to the limited categories of persons and under the conditions specified in § 20.84, special government employees, in § 20.85, other Federal government departments and agencies, in